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April 14, 2021

The Honorable Anna Eshoo
Chair
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
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Dear Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Subcommittee on Health:

My name is Jeffrey A. Singer. I am a Senior Fellow in Health Policy Studies at the Cato Institute. I am also a medical doctor specializing in general surgery and have been practicing that specialty in Phoenix, Arizona for over 35 years. I would like to thank the Subcommittee on Health for convening a hearing on Wednesday, April 14, 2021 on "An Epidemic Within a Pandemic: Understanding Substance Use and Misuse in America." I appreciate this opportunity to provide my perspective, as a health care practitioner and policy analyst, to assist this committee with its assessment of the current state of substance use and misuse in the United States.

The COVID-19 pandemic has diverted the nation's attention away from an overdose epidemic that was raging long before the appearance of the deadly virus and has accelerated during the viral pandemic. The Centers for Disease Control and Prevention reported last December that, after a brief pause in 2018, the overdose rate increased during 2019 by more than 5 percent to a total of 70,630. Overdose deaths due to opioids of any kind increased from roughly 47,000 to over 50,000, representing an increase of more than 6 percent. But illicit fentanyl and its analogs comprised more than 36,000 of all opioid overdose deaths, an increase of nearly 16 percent over one year, while heroin was responsible for approximately 14,000 (a roughly 7 percent decrease) and prescription opioids were found in just under 12,000 overdose deaths, representing a decrease of more than 7 percent. Methadone was found in a little more than 2,700 overdoses, a decrease of more than 10 percent. Perhaps even more alarming was that deaths due to psychostimulants such as methamphetamine and cocaine increased to historically high levels of more than 16,000, representing a nearly 24 percent jump in just one year.[1]

Now a study from the Commonwealth Fund suggests that overdose deaths may have increased by more than 27 percent in 2020, the year of the pandemic, to roughly 90,000 with opioids comprising 75 percent of overdose deaths and fentanyl and its analogs involved in 80 percent of opioid overdoses.[2]

All of this is occurring in the presence of a "war on drugs" that was declared by President Richard Nixon over 50 years ago and a "cold war" on prescription opioids that commenced over a decade ago.

Unfortunately, much of the nation's current policy rests on the mistaken narrative that the overdose crisis is largely the result of doctors overprescribing pain medications to their patients, creating a population of opioid addicts.

However, data provided by the CDC and the National Survey on Drug Use and Health, and reported in the peer-reviewed literature, clearly show there is no correlation between number of opioid prescriptions and the non-medical use of prescription opioids or opioid use disorder among persons age 12 and over. During a12-year period when prescription volume doubled, non-medical use and opioid use disorder rates remained essentially unchanged.[3] A study published in 2018 by public health researchers at Johns Hopkins and Harvard Universities reported on 568,000 "opioid naïve" patients prescribed prescription opioids for postoperative pain between 2008 and 2016 and found a total opioid misuse rate of 0.6 percent.[4] A study reported in the November 2019 *Annals of Emergency Medicine* found that only 1 percent of emergency department patients prescribed opioids for pain had "persistent use" of opioids six months later, and 80 percent of those were still suffering from their painful condition at the time.[5] And a study reported last month by researchers at Case Western Reserve University, University of Alabama at Birmingham, and American University of Antigua College of Medicine found that opioid morphine equivalent doses "did not show a statistically significant relationship with injury-related mortality, including with any subgroups of unintentional deaths, suicides, and homicides" in trauma patients.[6]

To be sure, the stress and isolation associated with the COVID-19 pandemic has increased substance use in general, and has made overcoming addiction more difficult, as evidence suggests that connectedness is crucial in the treatment of substance use disorder. Furthermore, interruptions or disruptions in rehabilitation programs and access to Medication Assisted Treatment for opioid use disorder have likely contributed to the rise in overdoses in 2020.

But in fact, as researchers at the University of Pittsburgh School of Public Health pointed out in 2018, the overdose crisis has been on a steady, exponential increase since at least the late 1970s, with different drugs dominating at any particular point in time.[7] An NBC News reporter covering the study stated, "It [the overdose crisis] started before the availability of synthetic opioids and may have only a little to do with the prescribing habits of doctors or the pushy habits of drugmakers, the team at the University of Pittsburgh found."[8] The researchers suggested that the overdose crisis may be driven by "an ongoing longer-term process" which may involve sociocultural dynamics. This suggestion helps explain why Cicero, et al of Washington University in St. Louis reported in November 2017 that more than 33 percent of heroin addicts entering rehab programs stated that their gateway drug—the drug with which they initiated drug use—was heroin, as opposed to just under 9 percent who initiated with heroin ten years earlier.[9]

Despite these findings, the bulk of public policy is aimed at reducing the number of opioids that physicians prescribe for their patients in pain. The CDC reports that total opioids prescribed per 100 persons peaked in the year 2012 and has decreased by 43 percent between 2012 and 2019 to a 14-year low.[10] Reports of chronic pain patients being cut off abruptly from their prescription opioids and desperately turning to the black market for relief or, even worse, to suicide, abound in the press.[11] Meanwhile, as the black market supply of diverted prescription opioids diminished starting around 2010, the proportion of overdose deaths attributable to diverted prescription opioids stabilized and then decreased while deaths due to, first, heroin, and later fentanyl began to rise as these drugs filled the void. And the overdose epidemic continues apace.

The ascendancy of fentanyl and the resurgence of methamphetamine-related deaths 15 years after Congress passed the Combat Methamphetamine Epidemic Act of 2005 should come as no surprise to those familiar with what has come to be called "The Iron Law of Prohibition," an application of what economists call the Alchian-Allen Effect.[12] Put simply, as law enforcement increases, the potency of the drug increases. As the term's author, Richard Cowan puts it, "the harder the enforcement, the harder the drugs."[13] When drugs are prohibited, they will be produced in more concentrated forms because they offer better efficiency by taking up less room in storage, less weight in transportation, and can be subdivided into smaller portions to generate more money. During alcohol prohibition, whiskey and other potent liquors were smuggled rather than beer or wine. Likewise, when people "tailgate" at football games, they drink beer or wine—but when they enter the stadium where it is not permitted to bring in alcohol, they tend to sneak in the "hard stuff."

The Iron Law of Prohibition explains the popularity that fentanyl and its analogs have with drug dealers: it is easily made in clandestine labs and mixed with heroin to increase its potency and reduce the size and weight needed to smuggle heroin across the border. Fentanyl is also smuggled across the border where it can be mixed with cocaine or methamphetamine (a preferred combination of people who like to "speedball") or pressed into counterfeit prescription pain pills. Restrictions to movement and travel arising from the COVID-19 pandemic have disrupted the supply chain for heroin. This has increased the utility of fentanyl and may be contributing to its predominance among the drugs causing overdose deaths.[14]

The Iron Law of Prohibition also explains why drug cartels have found more efficient means of producing more concentrated forms of methamphetamine, using substrates such as phenyl-2-propanone ("P2P") instead of relying on diverted over-the-counter Sudafed. Meanwhile, nasal congestion and allergy sufferers find it more difficult and inconvenient to obtain Sudafed, a very effective decongestant, which is behind-the-counter and controlled in most states, and prescription-only in Oregon and Mississippi.

I implore this Subcommittee to avoid attempts to "double down" on the policies that are clearly not reducing overdose deaths but are causing harm to innocent patients suffering from pain while making non-medical drug use even more dangerous and deadly.

Policy should avoid further attempts to codify the *2016 CDC Guideline for Prescribing Opioids for Chronic Pain*.[15] It must be stressed that the guidelines were never intended to be prescriptive, but rather suggestive. In fact, the authors of the guideline made clear that most of the recommendations were based on "Type 4 evidence," which was defined as evidence "in which one has very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of the effect."

The misinterpretation and misapplication of the 2016 CDC guidelines by lawmakers, insurance plans, pharmacies, and some practitioners caused the CDC to issue an advisory letter in 2019, urging against the guideline's misinterpretation and misapplication.[16] The guideline has come under criticism from multiple addiction and pain management specialists.[17] In June of 2020, Dr. James L. Madara of the American Medical Association wrote Dr. Deborah Dowell, the Chief Medical Officer of the CDC, stating that "patients experiencing pain should be treated as individuals, not according to one-size-fits-all algorithms and policies that do not take individual patient's needs into account." The letter went on: "Early on, the AMA feared that the arbitrary opioid analgesic dosage and quantity thresholds appearing in the CDC Guideline would cause unintended consequences when used to severely limit individual treatment decisions made by physicians…"[18]

The heavy reliance on Morphine Milligram Equivalent (MME) dosage to regulate prescribing has also come under heavy criticism from pharmacologists and pain specialists.[19] This reliance ignores the substantial genetic differences in drug metabolism between individuals. For example, the levels of the two primary enzymes that metabolize opioids can differ by 100-fold from one person to another, so the same dose of an opioid can be too low for a 100-pound woman and too high for a 250-pound man.[20]

We have seen during this pandemic how quickly our state of knowledge changes as more information about transmission, replication, and how to protect against the COVID-19 virus evolves. This applies as well to the state of knowledge that existed about the overdose epidemic when the CDC published its guideline in 2016. It would be unwise to codify a guideline that, at the time was admittedly based largely on Type 4 evidence, and is now 5 years old.

The 2016 Guideline recognized that one size does not fit all, and that individual context matters—which is why it was offered for consideration as a "rule of thumb" as opposed to absolute instructions. Codifying guidelines has the effect of casting them in stone. It makes nuance impossible. It incentivizes law enforcement agencies to view any deviation from the guidelines as a legal transgression and, as a result, frightens practitioners into abiding by guidelines at the expense of their best medical judgment.

I urge this Subcommittee to focus its efforts on harm reduction rather than on further punitive and restrictive measures.[21] One measure to consider is to require the Food and Drug Administration to reclassify the opioid antidote naloxone as over-the-counter.[22] The FDA has expressed a willingness to do so, but has been too deferential to the naloxone manufacturers, who may benefit financially by being able to charge higher prices to third-party payers because of naloxone's prescription requirement.[23]

Medication Assisted Treatment (MAT) with methadone or buprenorphine has been shown to be the only form of addiction rehabilitation to be associated with reduced overdose and opioid-related morbidity, when compared to opioid antagonist therapy (naltrexone), inpatient treatment, and intensive outpatient behavioral therapies, according to recent research reported in the *Journal of the American Medical Association*.[24] Yet because of the onerous requirement that practitioners get an "X-waiver" on their narcotics license from the Drug Enforcement Administration, only about 7 percent of practitioners are prescribing buprenorphine MAT. Furthermore, restrictions on the number of patients a practitioner may treat at any given time, along with restrictions on non-physicians engaging in buprenorphine MAT make matters worse. Congress should remove the X-waiver requirement. In the previous Congress this idea had bipartisan support.[25]

In addition, Congress should consider legislation to deregulate methadone treatment programs in order to allow outpatient prescription by primary care providers in an ambulatory setting. Methadone has been prescribed by primary care providers to treat addiction in Canada since 1963, in the U.K. since 1968, and in Australia since 1970.[26] A pilot program was undertaken with success by researchers at Boston University in conjunction with the Massachusetts Department of Public Health and reported in the *New England Journal of Medicine.*[27] A report last year by the National Academy of Sciences, Engineering, and Medicine also argued for allowing methadone treatment to be prescribed in primary care settings.[28]

Ordinarily, patients enrolled in methadone treatment programs must take the methadone—usually in liquid form—in the presence of treatment clinic staff. This implies distrust and reinforces the stigma attached to substance use disorder patients. It also makes compliance difficult. As an emergency measure to address the needs for isolation during the pandemic, the Substance Abuse and Mental Health Services Administration announced it will allow methadone clinics to dispense up to 28 days of take-home medication to patients.[29] Codifying that temporary administrative decision would be a step in the right direction.[30]

Congress should repeal the so-called "Crack House Statute," which stands in the way of cities that wish to establish Safe Consumption Sites, operating in over 120 locations in the developed world, including neighboring Canada, and proven since the early 1990s to be effective in reducing overdose deaths, blood-borne infectious diseases, and in bringing more people who suffer from substance use disorder into treatment.[31]

The previous administration encouraged the proliferation of syringe services programs, also known as "needle exchange programs," and this should continue. Unfortunately, many states have drug paraphernalia laws that stand in the way of the development of this federally legal and highly effective means of harm reduction. These same laws prevent the distribution of fentanyl test strips to opioid and psychostimulant users as well as operation of anonymous drug testing drop-off sites by harm reduction organizations.[32]

Finally, Congress should de-schedule marijuana. Among other benefits, this will facilitate research into the potential benefits of cannabis as a substitute for opioids in the treatment of pain as well as a potential adjunct in Medication Assisted Treatment.[33]

If Congress wishes to prevent a gathering tsunami of drug overdose deaths, it should end its focus on the number of pain pills practitioners prescribe to their patients. Instead, Congress should pivot to measures aimed at reducing harm to non-medical users who access increasingly dangerous drugs on the black market fueled by drug prohibition.

Respectfully submitted,

/s/

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